REMARKS

Claims 1, 2, 10-13, 15-22 and 24-31 are pending. Claim 28 has been amended to correct an obvious grammatical error. No new matter enters by this amendment.

I. Priority

Applicants reiterate their disagreement with the Examiner's contention that "applicant admitted on page 1 of the response filed 9/27/01 that SEQ ID NOs 4, 14, 27, 298, 311, 356, and 569 are not supported by the Provisional...." *See*, Response to Office Action dated April 2, 2003 at page 7. However, while disagreeing with the Examiner's contention, Applicants acknowledge the Examiner's stated position that claims 1-2, 10, 12, 16, 21, and 29, were "granted priority to 4/28/1998." Office Action at page 2. All other pending claims (i.e. claims 11, 13, 15, 17-20, 22-28, and 30-31) were granted priority to 4/28/1999. *Id.*

II. Rejection under 35 U.S.C. §101

Claims 1-2, 10-13, 15-22 and 24-31 stand rejected under 35 U.S.C. § 101 because the claimed invention allegedly is not supported by either a specific, substantial, and credible utility or a well-established utility. Applicants respectfully traverse this rejection.

The Examiner acknowledges that the specification describes multiple utilities for the present invention, including "to obtain nucleic acids from other species, to isolate promoters, to detect/identify polymorphisms, in genetic mapping, as molecular markers, to follow expression (e.g. to create an Expression Response), in hybridization

experiments, and in tissue printing." Office Action at page 3. However, the Examiner contends that none of the utilities disclosed in the present application satisfy 35 U.S.C. § 101 because "[t]hese are generic to the class of nucleic acids and are not specific, substantial and credible utilities for the SEQ ID NOs recited in the claims." *Id.*

The "basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility...where specific benefit exists in currently available form." *Brenner v. Manson*, 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). Applicants have met this part of the bargain – the present specification discloses nucleic acid molecules which, in their current form, provide at least one specific benefit to the public, for example, use to identify a polymorphism in a population of plants. *See, e.g.* Specification at page 67, line 3 through page 74, line 18. This benefit is specific, not vague or unknown, and it is a "real world" or substantial benefit.

The "threshold for utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). Furthermore, an invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983) ("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown").

The courts have expressed a test for utility that hinges on whether an invention provides an "identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364,

1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). For analytical purposes, the requirement for an "identifiable benefit" may be broken into two prongs: (1) the invention must have a specific, *i.e.*, not vague or unknown benefit, *In re Brana*, 51 F.3d 1560, 1565, 34 U.S.P.Q.2d 1436, 1440 (Fed. Cir. 1995); and (2) the invention must provide a real world, *i.e.*, practical or "substantial" benefit. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). A corollary to this test for utility is that the invention must not be "totally incapable of achieving a useful result," *i.e.*, the utility must not be incredible or unbelievable. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992).

The present specification discloses several uses for the claimed nucleic acid molecules, including use as nucleic acid molecule markers and probes (*see, e.g.*, specification at page 79, line 18 through page 80, line 5); to identify and obtain nucleic acid homologues (*see, e.g.*, specification at page 64, line 10 through page 65, line 20); in microarrays as gene-specific targets (*see, e.g.*, specification at page 85, line 6 through page 87, line 11); to identify the presence or absence of a polymorphism (*see, e.g.*, specification at page 67, line 3 through page 74, line 18); use to transform plants (*see, e.g.*, specification at page 92, line 1 through page 110, line 16); to determine the level or pattern of expression of a protein or mRNA associated with that nucleic acid molecule (*see, e.g.*, specification at page 80, line 6 through page 85, line 5); and use to overexpress or suppress a desired protein (*see, e.g.*, specification at page 110, line 12 through page 113, line 4).

The Examiner acknowledges that the nucleic acids of the present invention may be used as probes, to detect the presence or absence of polymorphisms, and in expression studies, however the Examiner maintains that these utilities are not "useful" because they are "applicable to the general class of nucleic acids". Office Action at pages 4-5. The Examiner also argues that "further research would be required to determine if any of the asserted utilities MAY be specific and substantial." Office Action at pages 4-5. Furthermore, although the Examiner admits that Applicants have pointed out that the nucleic acid molecules of the present invention comprise sequences that encode enzymes of the phosphogluconate pathway or fragments thereof, the Office Action alleges that the specification "does not actually disclose that any of the claimed SEQ ID NOs is known to encode an enzyme of the phosphogluconate pathway." Office Action at page 5.

The Examiner's assertions are not correct. The Examiner appears to be arguing that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. As stated in Applicants' Response to Office Action dated December 20, 2000, that position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result..."). Such an argument would imply that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. That position must be rejected as it requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303,

308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933).

Furthermore, the specification clearly asserts that the nucleic acid molecules of the present invention encode maize or soybean phosphogluconate pathway enzymes or fragments thereof. *See, e.g.,* specification at page 14, line 2 through page 15, line 2, page 222, line 8 through page 223, line 13 (Example 4), Table A and the sequence listing. The specification also explains the interrelationship of the enzymes involved in the phosphogluconate pathway (*see, e.g.,* specification at page 1, line 17 through page 4, line 20). In addition, the specification also discloses the methods used to analyze each of the claimed nucleic acid molecules and its association with the phosphogluconate pathway. *See, e.g.,* specification at page 15, line 21 through page 20, line 4 and Table A. One of ordinary skill in the art would recognize that the claimed nucleic acid molecules have utility, for example, to identify markers and isolate promoters in the phosphogluconate pathway of maize or soybean plants upon reading the present specification. These utilities are immediately apparent for the claimed nucleic acid molecules without further research.

The Examiner argues that the claimed nucleic acid molecules lack utility apparently because one would allegedly not be able to recognize an appropriate ATG codon or ORF for the claimed nucleic acid molecules. *See* Office Action at page 5. However, as stated above, one of ordinary skill on the art would clearly be able to ascertain these elements based on Applicants' disclosure (*see, e.g.,* specification at page 149, lines 16-18) and tools available to practitioners in the art, *e.g.,* BLASTX. Moreover,

the specification discloses that the nucleic acid molecules of the present invention encode phosphogluconate pathway enzymes or fragments thereof. Therefore, a complete ORF or start codon is not necessary for every claimed nucleic acid molecule. Furthermore, a complete ORF is not necessary to use the claimed nucleic acid molecules for the disclosed utilities, *i.e.,* as probes, to detect the presence or absence of polymorphisms, and in expression studies, all of which the Examiner acknowledges have been asserted in the specification.

In addition, for these reasons, the Examiner's assertion that homology "alone is not evidence that a particular protein is indeed encoded by a recited nucleic acid sequence" is irrelevant. Office Action at page 6. The Examiner has not provided any support for the proposition that the claimed nucleic acid molecules would not work for the recited utilities; or that one skilled in the art would doubt that the claimed nucleic acid molecules would work for the utilities disclosed in the present specification. To the contrary, the Examiner has acknowledged that "[i]t is possible that a claimed SEQ ID NO: encodes a fragment of an enzyme." Office Action at page 5. Applicants have thus provided sufficient evidence to lead a person of ordinary skill in the art to conclude that the asserted utilities are more likely than not true.

Applicants have disclosed several specific, substantial and credible utilities for the claimed nucleic acid molecules. Any one of these utilities is enough to satisfy the requirements of 35 U.S.C. § 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case, the rejection under

Section 101 is incorrect. Reconsideration and withdrawal of this rejection are respectfully requested.

III. Rejection under 35 U.S.C. § 112, first paragraph, Enablement

Claims 1-2, 10-13, 15-22 and 24-31 stand rejected under 35 U.S.C. § 112, first paragraph as not enabled because the claimed invention allegedly lacks utility. Office Action at page 6. Applicants respectfully traverse this rejection and contend that this rejection has been overcome by the arguments set forth above regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph is improper. Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

IV. Rejection under 35 U.S.C. § 112, first paragraph, Enablement

Claims 1-2, 22 and 24-25 stand rejected under 35 U.S.C. § 112, first paragraph, as the claimed subject matter allegedly is "not described in the specification in such a way as to enable one skilled in the art... to make or use the invention." Applicants respectfully traverse this rejection.

The Examiner asserts that "the claims are not enabled because neither the specification nor the prior art teach how to make the claimed enzymes from the SEQ ID NOs recited." Office Action at page 7. The Examiner also alleges that "homology alone is not evidence that a particular protein is indeed encoded by a recited nucleic acid sequence". *Id.* While the Examiner admits "Table A of the specification discloses that the claimed nucleic acid sequences encode the recited enzymes," the Examiner goes on to

assert, that the specification "does not disclose anywhere that the claimed nucleic acids actually encode any peptide or protein." *Id.*

First, Applicants disagree with these assertions. Second, Applicants respectfully point out that the claims are directed to nucleic acid molecules, not enzymes as alleged by the Examiner. Furthermore, Applicants assert that an analysis of the criteria presented by *In re Wands* supports Applicants' position that no undue experimentation would be required to make and use the claimed invention. *See In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1998).

The first *Wands* criterion is the quantity of experimentation necessary. The "make-and-test" quantum of experimentation is reduced by the extensive knowledge, *e.g.*, of conservative nucleotide substitutions, identification of an active site, and radiometric synthase assay conditions, to which a person of ordinary skill in the art has access. The Examiner asserts that undue experimentation would be required because "[t]he instant specification does not disclose any amino acid sequences" and, thus, it would allegedly require "undue experimentation for one skilled in the art to determine how to generate the peptides, with the functionality claimed, from the disclosed nucleic acid sequences." Office Action at page 7. However, one skilled in the art is sufficiently guided by Applicants' disclosure, which sets forth nucleic acid molecules as well as the enzymes or fragments thereof encoded by the nucleic acid molecules.

The Office Action further asserts that the "specification does not disclose or point to information with regard to activity assays, which would also be necessary to determine if any expressed protein actually is the enzyme recited." Office Action at page 8. As stated above, practitioners in the art are guided by the high level of skill in the art and the

present disclosure of the specification (*see, e.g.,* specification at page 110, lines 1-11). Performing routine and well-known steps, such as sequence alignment protocols, molecular weight determination, and antibody hybridization assays, cannot create undue experimentation even if it is laborious. *See In re Angstadt*, 537 F.2d 498, 504, 190 U.S.P.Q. 214, 218-219 (C.C.P.A. 1976).

The second and third *Wands* criteria relate to the amount of direction or guidance given, and the presence or absence of working examples. Again, the specification provides evidence of sequence identity, discloses start and stop positions within a sequence, and discusses the use of the claimed SEQ ID NOs to isolate additional sequences within a genome. *See, e.g.,* Examples 1-4, the sequence listing and Table A. Based on such disclosure, one of ordinary skill in the art would be enabled to make and use the invention commensurate in scope with the claims.

The fourth, fifth, and sixth *Wands* criteria focuses on the nature of the invention, the state of the art, and the relative skill in the art. The Examiner acknowledges the high level of skill in the art. Office Action at page 8. The specification provides a detailed description of the nucleic acid sequences required by the claims, and further describes amino acid sequences derived therefrom, and constructs and methods of use related thereto. *See, e.g.*, specification at page 46, line 6 through page 52, line 16 (describing polypeptide molecules encoded by the nucleic acid sequences of the present invention, homologues and other modifications, and methods of producing or expressing peptides or fragments of peptides), and page 92, line 1 through page 114, line 5 (describing use of the claimed nucleic acid molecules in methods of transforming plants). Practitioners in this art are guided by considerable knowledge and resources on the conditions and approaches

that can be utilized to identify, confirm, and introduce into other hosts, nucleic acid and amino acid sequences.

The seventh criterion considers the predictability of the art. The Examiner argues that the "one skilled in the art must 'guess' at some information (e.g., open reading frames, actual start codon, homology parameters) and/or develop new assays to arrive at the claimed invention". Office Action at page 8. Applicants respectfully disagree and assert, as discussed *supra*, that the specification discloses sufficient guidance to render the results of substitutions, additions, and deletions within the claimed nucleic acid molecules predictable. *See, e.g.,* specification at page 8, line 21 through page 13, line 21, page 48, line 6 through page 50, line 6 and page 149, line 10 through page 152, line 9. Furthermore, the specification provides sufficient guidance to one of skill in the art to decipher the information necessary to make and use the claimed nucleic acid molecules. *See, e.g.,* specification at page 149, line 10 through page 150, line 9 (describing software that can be used to identify open reading frames within the claimed nucleic acid molecules), and page 110, lines 1-11 (citing references to develop assays for gene expression).

The eighth criterion focuses on the breadth of the claims. Enablement is satisfied when the disclosure "adequately guide[s] the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility". *See In re Vaeck,* 947 F.2d 488, 496, 20 U.S.P.Q.2d 1438, 1445 (Fed. Cir. 1991). In the present case, one of skill in the art is specifically guided by the disclosure to look to, *e.g.*, sequence identity data in making that determination.

The Examiner has not met the evidentiary burden to impose an enablement rejection. A specification that discloses how to use a claimed invention "must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein." *In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995), *quoting In re Marzocchi*, 439 F.2d 220, 223, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971) (emphasis in original).

The Examiner has provided neither evidence supporting the rejection nor any explanation of why the specification allegedly fails to enable the nucleic acid molecules of claims 1-2, 22 and 24-25. *See In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (B.P.A.I. 1981) ("pure conjecture" does not substantiate rejection for lack of enablement). Therefore, because the above analysis illustrates that the specification clearly enables at least the methods of making and using the invention as set forth in the Examples, and the claims, the enablement requirement has been satisfied. *Cf. Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) ("the enablement requirement is met if the description enables any mode of making and using the invention") (emphasis added), *quoting Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991). Accordingly, Applicants respectfully request reconsideration and withdrawal of the enablement rejection under 35 U.S.C. § 112, first paragraph.

V. Rejection under 35 U.S.C. § 112, first paragraph, Written Description

Claims 1-2, 10-13, 15-22 and 24-30 stand rejected under 35 U.S.C. § 112, first paragraph because the claimed subject matter allegedly was "not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Office Action at page 8. Applicants respectfully traverse this rejection.

The Examiner, acknowledging that "[s]equences consisting of SEQ ID NOs 1, 4, 14, 27, 225, 298, 311, 356, 569, and 619 meet the written description requirement," does not dispute that Applicants had possession of and have adequately described the claimed SEQ ID NOs. *Id.* However, the Examiner argues that Applicants have allegedly not described the claimed nucleic acid molecules. The basis for the Examiner's rejection is that the specification allegedly "sets forth a list of possible variations for the inventive sequences, . . .but does not actually describe, by sequence or structure, any of the variations, nor does the specification disclose any longer sequences (e.g. genomic) which may comprise the claimed sequences." *Id.* According to the Examiner, the sequences recited in the claims do not appear to comprise ORFs or encode proteins, and encompass much larger sequences which may encode different proteins from those recited. Apparently, the Examiner contends that the specification allegedly "provides insufficient written description to support the genus encompassed by the claim." *Id.* at page 9. Applicants respectfully disagree and maintain the position set forth in the response filed April 2, 2003.

As Applicants have previously argued, this argument conflicts with existing patent jurisprudence. It is well-established law that use of the transitional term

"comprising" leaves the claims "open for the inclusion of unspecified ingredients even in major amounts." *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986). The very nature of "unspecified ingredients" is that they are not specified or described. The Examiner attempts to turn the legal meaning of "comprising" on its head by requiring Applicants to describe hypothetical claim elements. The Examiner alleges that because "at least claims 1-2, 22, 24, and 25 recite nucleic acids which encode proteins... they are directed to nucleic acids which necessarily comprise ORF's." Office Action at page 9. Applicants maintain that the claims recite the required nucleic acid sequences, define the enzyme or fragment thereof encoded by the sequences, and recite hybridization parameters. Applicants' claims do not recite open reading frames and, accordingly, need not describe them. Applicants need only describe the claimed invention, and have done so in the present application.

Applicants reiterate that the purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventors had

possession of the claimed invention, even if not every nuance, then the written description has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. A person of ordinary skill in the art would, after reading the present specification, understand that Applicants had possession of SEQ ID NOs: 1, 4, 14, 27, 225, 298, 311, 356, 569, and 619, complements and variations thereof, sequences that hybridize to the claimed nucleic acid molecules under the recited conditions, as well as the enzymes, or fragments thereof, they encode. Applicants have indeed demonstrated possession of the claimed invention.

For example, the specification describes gene sequences, corresponding sequences from other species, mutated sequences, SNPs, polymorphic sequences, promoter sequences, exogenous sequences, and so forth (*see, e.g.,* specification at page 23, line 12 through page 26, line 20; page 46, line 6 through page 48, line 5; page 53, line 10 through page 54, line 22; and page 65, line 21 through page 74, line 18). The specification also describes appropriate hybridization conditions (*see, e.g.,* specification at 43, line 13 through page 45, line 4); nucleic acid molecules comprising nucleic acid sequences having conservative variations or encoding amino acid sequences having conservative substitutions (*see, e.g.,* specification at page 48, line 6 through page 50, line 6); fusion protein or peptide molecules or fragments thereof encoded by the nucleic acid molecules of the present invention (*see, e.g.,* specification at page 59, lines 4-15); plant homologue proteins (*see, e.g.,* specification at page 59, line 16 through page 60, line 6); site directed mutagenesis of the claimed nucleic acid molecules (*see, e.g.,* specification at page 87, line 12 through page 89, line 3); vectors comprising the claimed nucleic acid molecules and methods of transforming plants (*see, e.g.,* specification 93, line 1 through page 107, line 19); and construction of cDNA libraries using the claimed nucleic acid

molecules (*see, e.g.,* specification at page 152, line 13 through page 222, line 7 (Examples 1-3)).

Thus, Applicants respectfully disagree with the Examiner's contention that despite the numerous variations of the claimed nucleic acid molecules described in the present specification, "with the exception of sequences consisting of SEQ ID NOs 1, 4, 14, 27, 225, 298, 311, 356, 569, and 619, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides". Office Action at page 11. The Examiner appears to assert that each nucleic acid molecule within a claimed genus must be described by its complete structure. This assertion is unfounded. The test, promulgated by the Federal Circuit, stipulates that where a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus, written description is satisfied. *See Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). In the present case, Applicants have satisfied that test for written description by providing a structural feature, namely nucleic acid molecules that distinguish members of the claimed genera from non-members.

Applicants maintain that they have provided a representative number of detailed chemical structures, i.e., the nucleic acid sequences of SEQ ID NOs: 1, 4, 14, 27, 225, 298, 311, 356, 569, and 619, and their complements, as well as recited specific hybridization conditions. The common structural feature (the nucleotide sequence of SEQ ID NOs: 1, 4, 14, 27, 225, 298, 311, 356, 569, 619 and their complements) is shared by every nucleic acid molecule in the claimed genera, and this feature distinguishes

members of the claimed genera from non-members. For example, if a nucleic acid molecule such as an mRNA contains the nucleotide sequence of SEQ ID NO: 1, then it is a member of the claimed genus of nucleic acid molecules comprising a nucleic acid sequence of SEQ ID NO: 1.[1] If a nucleic acid molecule does not contain SEQ ID NO: 1, then it is not a member of that claimed genus. The presence of other nucleotides at either end of the recited sequence will not interfere with the recognition of a claimed nucleic acid molecule as such – it either contains the nucleotides of SEQ ID NO: 1 or it does not. Accordingly, the standard elucidated in *Lilly* for the written description requirement has been met.

Moreover, closely related nucleic acid molecules falling within the scope of the present claims are readily identifiable - they either hybridize under the claimed conditions to SEQ ID NOs: 1, 4, 14, 27, 225, 298, 311, 356, 569 and 619 (or complements thereof) or they do not. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the specification.

Furthermore, nucleic acid molecules within the scope of the instant claims are also readily identifiable as they either encode a maize or soybean phosphogluconate pathway enzyme or fragment thereof or they do not. Claims 1-2, 22, 24, and 25 are directed to "substantially purified nucleic acid molecules that encode a maize or soybean"

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[1] The same argument applies with equal force to every genus of the claimed nucleic acid molecules. For example, if a nucleic acid molecule such as an mRNA comprises the nucleotide sequence of SEQ ID NO: 4, then it is a member of the claimed genus of nucleic acid molecules comprising a nucleic acid sequence of SEQ ID NO: 4. *See, e.g.,* claim 13.

phosphogluconate pathway enzyme or fragment thereof. Applicants respectfully submit that the present specification complies with the written description requirement by describing nucleic acid sequences that encode maize or soybean phosphogluconate pathway enzymes or fragments thereof. *See, e.g.*, Table A. Descriptions of ORFs are not required to comply with the written description requirement.

Applicants maintain their disagreement with the Examiner's application and characterization of Baker with respect to Applicants' disclosure. Office Action at pages 10-11. First, the Examiner's assertion that "Applicant acknowledges that BAKER et al... is directed to controversy in the art over prediction of function based on homology alone" misconstrues Applicants' stated position. *See* Office Action at page 10 (citations omitted). In fact, the actual statement made by Applicants in the Amendment and Response filed October 17, 2002, was that "Applicants contend that this article is directed to the controversy in the art in general over prediction of function based on homology alone, but does not take into consideration Applicants' disclosure." Response filed October 17, 2002, at page 5 (emphasis in original). The Examiner relies on Baker to support a broad allegation of unpredictability in the art, but has not presented any support or given any reason of how Baker is specifically applicable to Applicants' invention, or why this reference would support a written description rejection under 35 U.S.C. § 112, first paragraph. A general allegation of unpredictability in the art does not form a basis for a proper written description rejection. *See* M.P.E.P. § 2163 at 2100-170.

Applicants reiterate that the present specification discloses that the claimed SEQ ID NOs exhibit a range from about 44% to about 72% sequence identity, using a

BLASTX or BLASTN comparison, to a maize or soybean phosphogluconate pathway enzyme, or fragment thereof. *See* Table A. Baker, *et al.* teaches that this is considered a "high-accuracy" comparative model. Baker *et al.,* at page 93. Moreover, Example 4 delineates the methods used to generate the homology in Table A. The Examiner has offered no evidence to demonstrate, in light of Applicants' disclosure, why one of ordinary skill in the art would reasonably doubt that a nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NOs: 1, 4, 14, 27, 225, 298, 311, 356, 569, 619 or the complements thereof would encode a maize or soybean phosphogluconate pathway enzyme or fragment thereof and, as such, has not met the burden to impose a written description rejection.

The Examiner would require a "comparison of binding regions, conserved regions, catalytic regions, etc. to support that the peptides putatively encoded by the claimed SEQ ID NOs would be expected to actually exhibit" enzyme activity. Office Action at page 10. Such a requirement is beyond the written description requirement. Applicants have described nucleic molecules that encode phosphogluconate pathway enzymes or a fragment thereof. *See, e.g.*, Table A. That is all that is required under 35 U.S.C. § 112, first paragraph.

The fundamental factual inquiry for satisfying the written description requirement is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, that applicants were in possession of the invention as now claimed. See, *e.g.*, *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 U.S.P.Q.2d 1111, 1117 (Fed. Cir. 1991). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations. *Lockwood v. American*

Airlines, Inc., 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997), M.P.E.P. § 2163.02. Moreover, the Examiner has failed to provide reasons why a person skilled in the art at the time the application was filed would not have recognized that Applicants were in possession of the invention as claimed in view of the disclosure of the application as filed. "A general allegation of 'unpredictability in the art' is not a sufficient reason to support a rejection for lack of adequate written description." MPEP § 2163 at 2100-170.

For these same reasons, the Examiner's rejection of claims 1, 22, 24 and 25 for lack of adequate written description, *see* Office Action at page 11, must also fail as it too overreaches the requirements of the law. Simply put, Applicants have described the invention encompassed by the claims. No more is required.

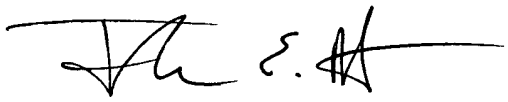
The Examiner has offered no evidence to demonstrate, in light of Applicants' disclosure, why one of ordinary skill in the art would reasonably doubt that the invention encompassed by Applicants' has not been adequately described in the present disclosure. As such, the Examiner has not met the burden to impose a written description rejection.

Based on the foregoing, Applicants respectfully submit that the currently pending claims are supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112. As such, reconsideration and withdrawal of the outstanding written description rejection are respectfully requested.

Conclusion

In view of the foregoing remarks, Applicants respectfully submit that the present application is now in condition for allowance, and notice of such is respectfully requested. The Examiner is encouraged to contact the undersigned should any additional information be necessary for allowance.

Respectfully submitted,



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